

Comparing zanubrutinib versus combination chemotherapy as treatment for untreated chronic lymphocytic leukemia or small lymphocytic lymphoma

SUMMARY DATE December 2021

KEY TAKEAWAYS

After two years, more patients with untreated chronic lymphocytic leukemia or small lymphocytic lymphoma who took zanubrutinib were alive without their cancer growing or spreading compared with patients who had combination chemotherapy (bendamustine + rituximab).

INTRODUCTION What is chronic lymphocytic leukemia or small lymphocytic lymphoma?

- ▶ Chronic lymphocytic leukemia or small lymphocytic lymphoma (also known as CLL and SLL) are a type of slow-growing blood cancer where an increased number of mature, but cancerous, lymphocytes are found in the blood and bone marrow, and/or in the lymph nodes
 - ▶ Lymphocytes are a type of white blood cell that normally produces antibodies that defend the body from germs
- ▶ CLL and SLL are essentially the same disease, the only difference being the location in the body where the cancer primarily occurs
 - ▶ CLL is when most of the cancer cells are in the bloodstream and the bone marrow
 - ▶ SLL is when most of the cancer cells are located in the lymph nodes and are rare in the blood

What is zanubrutinib?

- ▶ Zanubrutinib, sold under the brand name BRUKINSA[®], is a Bruton's tyrosine kinase (BTK for short) inhibitor
 - ▶ Bruton's tyrosine kinase is a protein found in a type of white blood cell that plays a role in cell development and survival
 - ▶ Inhibiting BTK function can keep cancer cells from growing and lead to death of cancer cells

What was the aim of this study?

- ▶ The SEQUOIA study compared the treatment effects and side effects of zanubrutinib with the combination chemotherapy in patients with untreated CLL/SLL
 - ▶ Treatment effect is how well the drug works treating the disease
- ▶ Patients who received combination chemotherapy were given rituximab (an antibody) and bendamustine (a drug compound) at the same time

What does this summary describe?

- ▶ This summary describes the treatment effects and side effects of zanubrutinib and combination chemotherapy in patients with untreated CLL/SLL. It looks at:
 - ▶ Which treatment gave patients a lower chance of the cancer growing or spreading over time
 - ▶ How many patients were alive without their cancer growing or spreading after 2 years
 - ▶ What side effects were common with each treatment

PHONETICS

Bendamustine
<BEN-duh-MUS-teen>

BRUKINSA
<BROO-kin-suh>

Lymphocytic leukemia
<LIM-foh-SIH-tik loo-KEE-mee-uh>

Rituximab
<rih-TUK-sih-mab>

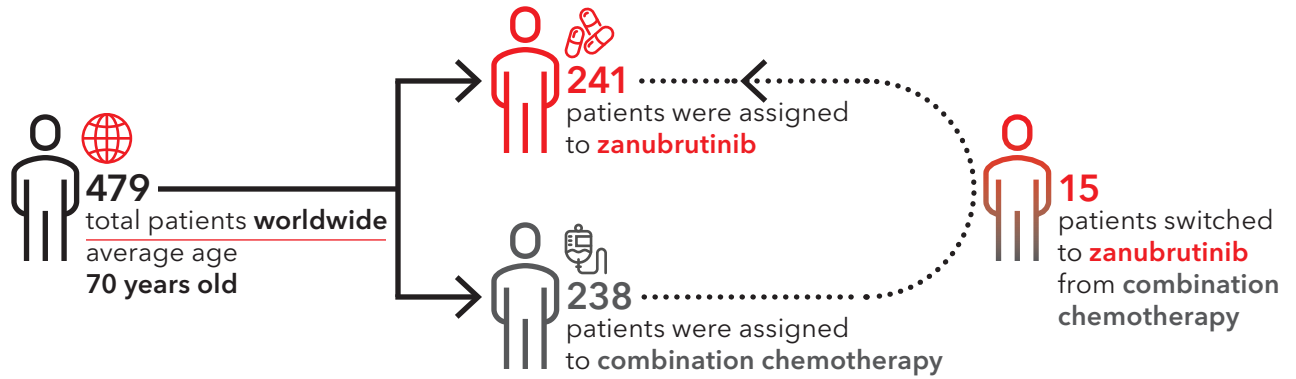
Tyrosine kinase inhibitor
<TY-ruh-seen KY-nays in-HIH-bih-ter>

Zanubrutinib
<ZAN-yoo-BROO-tih-nib>



Zanubrutinib **is not** approved outside of China as a therapy for untreated chronic lymphocytic leukemia or small lymphocytic lymphoma, which is discussed in this summary. This summary reports the results of a planned interim analysis of the study, meaning that the study is still ongoing.

STUDY DETAILS Who took part in the study?



Patients missing a piece of their DNA in chromosome 17, a DNA mutation that is common in CLL/SLL, were not eligible for this study.

What were the results of the study?

58% LOWER CHANCE

After 2.2 years of follow-up, patients on **zanubrutinib** had a **lower chance** of their cancer growing or spreading versus patients receiving **combination chemotherapy**

- After two years**
- About **14** of every 100 patients who took **zanubrutinib** died or had their cancer grow or spread
 - About **30** of every 100 patients who received **combination chemotherapy** died or had their cancer grow or spread

Most common side effects were*	Zanubrutinib	Combination Chemotherapy
Low number of infection-fighting white blood cells called neutrophils	15%	57%
Feeling sick to the stomach	10%	33%
Fever	7%	26%
Rash	11%	19%
Trouble having a bowel movement	10%	19%
Low number of red blood cells	5%	19%
Infusion-related reactions	<1%	19%
Feeling tired	12%	16%
Vomiting	7%	15%
Upper respiratory tract infection	17%	12%
Bruising	19%	4%

*These side effects occurred in at least 15% of patients who took zanubrutinib or received combination chemotherapy.

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CONCLUSIONS

- ▶ In patients with untreated CLL/SLL, the chance of CLL/SLL growing or spreading over time was **lower** in patients who took zanubrutinib than with combination chemotherapy
- ▶ After two years, **more patients** who took zanubrutinib than received combination chemotherapy were still alive without their cancer growing or spreading

MORE INFORMATION

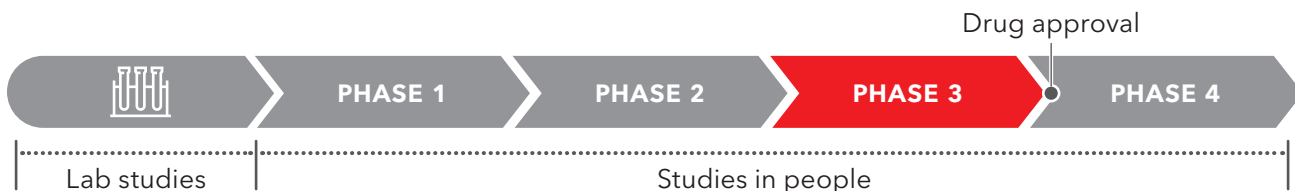
Who sponsored the study?

This study was sponsored by BeiGene, Ltd. BeiGene would like to thank the trial investigators, site support staff, and especially the patients who took part in the study.

Disclosure information

This summary was prepared by Regina Switzer, PhD (BeiGene, Ltd.). The authors of the full presentation have reviewed and approved this summary.

Where is this study in development?



Are there plans for additional studies?

This study is ongoing and has not yet been completed. Other zanubrutinib studies are currently ongoing and can viewed by going to <https://www.beigenemedical.com/pipeline>.

Additional study information

Full study title: SEQUOIA: Results of a Phase 3 Randomized Study of Zanubrutinib versus Bendamustine + Rituximab in Patients with Treatment-Naïve Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

For detailed study information, go to: <https://clinicaltrials.gov/ct2/show/NCT03336333>

For more information about scientific studies in general, go to:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>

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